

includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; Report by the Dose Reconstruction Review Methods Work Group; SEC Petitions Update; Site Profile reviews for: Dow Chemical Co. (Madison, Illinois), and General Steel Industries (Granite City, Illinois); SEC petitions for: Battelle Laboratories, King Avenue (1956–1970; Columbus, Ohio), Lawrence Livermore National Laboratory (1974–1995; Livermore, California), Blockson Chemical Co. (1960–1991; Joliet, Illinois), Rocky Flats Plant (1984–1989; Golden, Colorado), Idaho National Laboratory (1949–1970; Scoville, Idaho), and Kansas City Plant (1949–1993; Kansas City, Missouri); and Board Work Sessions.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted to the contact person well in advance of the meeting. Any written comments received will be provided at the meeting in accordance with the redaction policy provided below.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter.

(2) If an individual in making a statement reveals personal information (e.g., medical or employment information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information.

(3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriated, such information will be redacted, unless the disclosure is made by the third party's authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

(4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or

the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure.

The Board will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings.

Contact Person For More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E-20, Atlanta, Georgia 30333, telephone: (513) 533-6800, toll free: 1-800-CDC-INFO, email: [dcas@cdc.gov](mailto:dcas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Catherine Ramadei,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Meeting: Clinical Laboratory Improvement Advisory Committee**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

**Times and Dates**

8:30 a.m.–5 p.m., November 18, 2015.  
8:30 a.m.–12 p.m., November 19, 2015.

*Place:* CDC, 2500 Century Center Boulevard, Rooms 1200/1201, Atlanta, Georgia 30345.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. This meeting will also be webcast, please see information below.

*Purpose:* This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic transmission of laboratory information.

*Matters for Discussion:* The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include laboratory information exchange (interoperability); noninvasive prenatal testing; CLIA waiver guidance; the Institute of Medicine (IOM) report "Improving Diagnosis in Health Care;" and FDA guidance for laboratory developed tests.

Agenda items are subject to change as priorities dictate.

*Webcast:* The meeting will also be webcast. Persons interested in viewing the webcast can access information at: <http://cdclabtraining.adobeconnect.com/novcliac/>.

*Online Registration Required:* All people attending the CLIA meeting in-person are required to register for the meeting online at least 5 business days in advance for U.S. citizens and at least 10 business days in advance for

international registrants. Register at: <http://www.cdc.gov/cliac/Meetings/MeetingDetails.aspx#>. Register by scrolling down and clicking the "Register for this Meeting" button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than November 13, 2015 for U.S. registrants and November 8, 2015 for international registrants.

**Providing Oral or Written Comments:** It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments on agenda items whenever possible.

**Oral Comments:** In general, each individual or group requesting to make oral comments will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, speakers should notify the contact person below at least one week prior to the meeting date.

**Written Comments:** For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, to include the original signature of the submitter, should be provided to the contact person at the mailing or email address below, and will be included in the meeting's Summary Report.

**Availability of Meeting Materials:** To support the green initiatives of the federal government, the CLIAC meeting materials will be made available to the Committee and the public in electronic format (PDF) on the internet instead of by printed copy. Check the CLIAC Web site on the day of the meeting for materials: [http://www.cdc.gov/cliac/cliac\\_meeting\\_all\\_documents.aspx](http://www.cdc.gov/cliac/cliac_meeting_all_documents.aspx).

**Note:** If using a mobile device to access the materials, please verify that the device's browser is able to download the files from the CDC's Web site before the meeting. Alternatively, the files can be downloaded to a computer and then emailed to the portable device. An internet connection, power source, and limited hard copies may be available at the meeting location, but cannot be guaranteed.

**Contact Person for Additional Information:** Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and

Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F-11, Atlanta, Georgia 30329-4018; telephone (404) 498-2741; or via email at [NAnderson@cdc.gov](mailto:NAnderson@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for CDC and the Agency for Toxic Substances and Disease Registry.

**Catherine Ramadei,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0536]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3601, entitled "Medical Device User Fee Cover Sheet," which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

**DATES:** Submit either electronic or written comments on the collection of information by December 21, 2015.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

**Instructions:** All submissions received must include the Docket No. FDA-2012-N-0536 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including